



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2003

Assurance Medical, Inc.
c/o Mr. Howard Holstein
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004

Regulation Number: 21 CFR §884.2990
Classification: II
Product Code: 85 NKA

Re: K010514 - Automatic Evaluation of Class III Designation
BreastView® Visual Mapping System

Dear Mr. Holstein:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the BreastView® Visual Mapping System that is intended for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast examination. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the BreastView® Visual Mapping System and substantially equivalent devices of this generic type into class II under the generic name, Breast lesion documentation system. This order also identifies the special controls applicable to this type of device.

FDA identifies this generic type of device as:

884.2990 Breast lesion documentation system

A Breast lesion documentation system is a device for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast examination.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. If approved, this classification shall be the initial classification of the device. Within 30 days after the issuance of an approval order classifying the device, FDA must publish a notice in the **Federal Register** of the classification of the device type.

On May 28, 2002, FDA filed your petition requesting classification of the BreastView® Visual Mapping System into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on April 30, 2002, automatically classifying the BreastView® Visual Mapping System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the BreastView® Visual Mapping System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of this type of device for its intended use.

After review of the information submitted in the petition, FDA has determined that the BreastView® Visual Mapping System intended for use in producing a surface map of the breast as an aid to document palpable breast lesions identified during a clinical breast exam can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of this type of device. Therefore, in addition to the general controls of the act, the BreastView® Visual Mapping System is subject to the following special controls: *Class II Special Controls Guidance Document: Breast Lesion Documentation System; Guidance for Industry and FDA.*

The Class II Special Controls Guidance Document identifies the following potential risks presented by the device:

1. Failure to produce an appropriate map;
2. Misinterpretation of displayed images;
3. Improper Use;
4. Skin irritation or toxicity;
5. Electrical Shock;
6. Electromagnetic Interference; and
7. Tissue trauma from mechanical injury.

FDA believes the following controls identified in the Class II Special Controls Guidance Document, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of this type of device:

1. Recommendations for labeling;
2. Information on material safety;
3. Performance Characteristics;
4. Bench testing; and
5. Software Information.

Following the effective date of a final rule reclassifying the device, any firm submitting a 510(k) premarket notification for a breast lesion documentation system will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

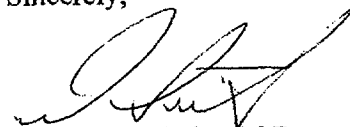
Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the breast lesion documentation system they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Mr. Colin Pollard at 301-594-1180.

Sincerely,



Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health